

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:)	
)	
Uber, III et al.)	
)	Art Unit: 3737
Serial No. 09/545,582)	
)	Examiner: R. Smith
Filed: April 7, 2000)	
)	
For: Patient Infusion System for Use)	
With MRI)	

DECLARATION OF SALVATORE J. DEDOLA PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

I, Salvatore J. Dedola, hereby declare that:

1. I am a resident of New Kensington, Pennsylvania and have been working as a mechanical design engineer or a supervisor for a mechanical design and manufacturing engineering groups for over 25 years. In 1980, I received my Bachelor of Science degree in Mechanical Engineering from the University of Pittsburgh. I also received a Master of Business Administration degree from the University of Pittsburgh in 1998.

2. I am currently the manager of the Sterile Disposables Manufacturing engineering department at Medrad, Incorporated ("Medrad"). I began working as a mechanical design engineer for Medrad in 1987. Since then I have held the positions of senior mechanical engineer, project engineer, senior project engineer, Mechanical Design Engineering Manager and Program Manager as well as my current position.

3. Prior to working at Medrad, I was a mechanical design engineer for ALCOA where I designed in-plant equipment, a mechanical design engineer for Molytek where I designed manufacturing fixtures and a mechanical design engineer for Vamco where I designed high speed press feeds.

4. I am a named inventor of U.S. Pat. App. No. 09/545,582, entitled "Patient Infusion System for Use with MRI," hereinafter referred to as the Patent Application.

5. Based on my technical education as well as my many years of technical experience in the field, I was at the time of the invention in the Patent Application and I still am a person of ordinary skill in the art of designing and developing patient infusion systems used with MR imaging procedures. In particular, I am familiar with the development of the patient infusion system which forms the basis of the Patent Application. I helped design and develop the system encompassed by the Patent Application, I assisted with the lengthy and difficult process of designing and testing prototype devices and I am familiar with the delay by other manufacturers in developing a competitive product.

6. The challenging design and development process and the difficulties experienced by other manufacturers in developing a competitive product are briefly described below.

The Development Process and Design Challenges

7. When I began my employment at Medrad, I worked on the design for a patient infusion system for use with MRI that resulted in the invention claimed in the Patent Application. I was responsible for, among other things, the non-magnetic injector head of the infusion system. My work included the designing an injector head that would not create extraneous electromagnetic interference with the MRI scanner and would not be adversely affected by the high strength of the high magnetic field of the imaging system. I was also involved in other design aspects.

8. The design of the infusion system took several years to complete. During the design, many obstacles were encountered. It was difficult to design a power injector - an electro-mechanical device - that could operate effectively in a hostile environment such as the MR imaging suite. The MR environment presented at least two challenges. The first challenge was to ensure that the operation of the device would not create spurious electromagnetic interference (EMI) that would significantly reduce the diagnostic capabilities of the MRI system. EMI can cause "artifacts" that mar and distort MR images, impairing the ability of physicians to use the images for diagnostic purposes. The second challenge was to design a device that would not be adversely affected by the strong magnetic fields emitted by the MR imaging system - *i.e.* so that the injector would still operate effectively during the operation of the MRI. These challenges required design solutions such as distributing the control aspects of the injection system between

components that resided inside the shielded room and inside the control room (outside the shielded room), configuring the system so that control signals were transmitted across the communication link that spanned the shielded wall, and using communication transmission techniques that would not interfere with, or be interfered by, the MRI system.

9. Another design concept that was new to this invention and difficult to implement was the use of two syringes that could be simultaneously engaged by drive mechanisms of the injector. By having two syringes engaged in this manner, it was possible to operate the injector to smoothly transition from injecting contrast fluid from one syringe into the patient, to injecting saline solution from the other syringe (or vice versa).

10. Part of the development process for the invention claimed in the Patent Application included designing prototypes and testing those prototypes in the field. The experimentation process spanned at least three different iterations of prototypes and took many years to complete. The feedback from this process allowed us to improve and refine the device and arrive at the design disclosed in the Patent Application.

Commercial Success of Products Embodying the Claimed Invention

11. Medrad sold its first MR power injector, the Spectris, in March 1996 following approval by the U.S. Food and Drug Administration ("FDA") in September 1995. The Spectris consisted of a display control console, master control unit and battery charging unit that were used in the control room of the MR suite; an injector head stand, and head control unit that were used in the scan room; and an optical transmitter receiver pair that provided communications between the modules in the two rooms. Since the Spectris was introduced into the market, it has

experienced a high level of commercial success, attributable to the invention embodied by the Patent Application.

12. The Spectris embodies the patient infusion system for use with MRI that is disclosed in the Patent Application, and that system has proven to work effectively in conjunction with MRI imaging procedures. The overwhelming commercial success of the Spectris is attributable to the invention disclosed and claimed in the Patent Application.

13. Medrad developed a new MR injector called the Spectris Solaris injector and introduced it in 2002. The Spectris Solaris injector also embodies the claimed invention in the Patent Application. The Spectris Solaris has experienced a high level of commercial success as well.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: May 24, 2007

A handwritten signature in black ink, appearing to read 'S. Dedola', written over a horizontal line.

Salvatore J. Dedola
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